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COMPLIANCE 101

Hitting the ground running—What every new (or wannabe) compliance professional needs to know

By Kathleen Duffett, RN, JD

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In the beginning…

About ten years ago, I was working in the risk management department of a major medical center. Although I enjoyed my job, I wanted to branch out into something new and, if possible, make a few more dollars. As I started to get the word out that I was looking, a friend of mine who worked for a large consulting firm called me. "We do corporate compliance work for health care businesses – why don't you submit your resume?" Not knowing much about corporate compliance, but interested in a new opportunity, I sent in my resume and got an interview. Now I needed to beef up on corporate compliance issues, fast! I relied on some materials I had received at a fraud and abuse law conference I had attended a couple of years earlier. That got me through the interview (barely, I am sure) and I got the job. Now I needed a crash course in compliance basics a.s.a.p.! Although I found plenty of sophisticated articles about specific corporate compliance issues, it was almost impossible to find "beginner's information" regarding common corporate compliance issues. This article is just that—a down and dirty primer on corporate compliance issues for the new (or wannabe) compliance professional.

Brief history of health care compliance

Health care fraud and abuse became the focus of the federal government in the 1990s. With medical costs escalating, the federal government was paying out big bucks through its health care programs and wanted to ensure that its increasing costs were not the result of fraud and abuse. In the mid-1990s, the Department of Justice (DOJ) announced that combating health care fraud was its number two priority, second only to combating violent crime.

Most of the federal health care-related legislation passed in the 1990s, in particular the Health Insurance Portability and Accountability Act of 1996 (HIPAA), included anti-fraud and abuse measures. This legislative trend has continued into the present. In addition, since the 1990s, most fraud and abuse legislation includes appropriations to fund prevention activities. State governments have also become more active in the fight against fraud and abuse in relation to their Medicaid and other state run programs.

Health care organizations have responded to all this federal and state activity by instituting corporate compliance programs. Why? In the event that a health care organization is found guilty of wrongdoing, an effective compliance program can reduce the organization's exposure to criminal sanctions, civil damages and penalties, and administrative remedies.

Federal & State agencies involved in combating fraud

A multitude of federal and state agencies are involved in the fight against fraud and abuse. The agencies on the forefront of this effort include:

Office of the Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS)

The OIG is an independent unit within HHS. It functions as a watchdog. The responsibilities of the OIG include conducting audits and investigations related to HHS operations and programs (such as Medicare and Medicaid); preventing and detecting fraud and abuse; issuing guidelines and parameters outlining activities that constitute fraud and abuse; and keeping the Secretary of HHS and Congress informed about problems and issues related to the administration and operations of HHS programs.

The OIG is an extremely active agency and is a leading authority on health care fraud and abuse issues.

The U.S. Department of Justice (DOJ)

Most people associate the DOJ with terrorism and related matters. However, the DOJ is actively involved in combating health care fraud and abuse. Historically, the primary focus of the DOJ has been the investigation and prosecution of health care organizations for violations of the federal False Claims Act.

State Medicaid Fraud Control Units (MFCUs)

Almost every state has its own MFCU. New York State has the largest (and most highly regarded) MFCU. The MFCUs are involved in the investigation and prosecution (or referral for prosecution) of various illegal activities, such as kickbacks and improper billings, perpetrated by health care providers and others who participate in a state's Medicaid program. Most MFCUs are part of the state attorney general's office. A small number of the units are located in various other state agencies.

State Attorneys General Offices

In addition to running MFCUs, many state attorneys general get involved in fraud and abuse issues, particularly in managed care. Using consumer protection and other applicable state laws, they target health plans, providers, and other players in the health care

industry who engage in fraudulent, misleading, deceptive, or illegal practices.

Seven basic elements in all compliance programs

In the federal court system, wrongdoers are punished in accordance with the Federal Sentencing Guidelines (FSGs). Under the FSGs, an organization that has an effective compliance program can reduce its exposure to civil damages, penalties, criminal sanctions, and administrative penalties (e.g., exclusion from participation in federal health care programs). The OIG's voluntary Compliance Program Guidances (CPGs), which provide the OIG's perspective on what constitutes an effective compliance program, are based on the FSG's seven basic elements:

1. Establishing written compliance standards and procedures to be followed by employees and other agents (e.g., policies and procedures, code of conduct);
2. Making high-level personnel responsible for overseeing compliance (e.g., compliance officer, compliance committee);
3. Developing and implementing training and education programs for all employees;
4. Developing effective lines of communication (e.g., hotlines, protection for whistleblowers);
5. Taking reasonable steps to achieve compliance with standards, including use of monitoring and auditing systems;
6. Consistently enforcing the standards through appropriate disciplinary mechanisms; and
7. Responding promptly to detected offenses and taking all reasonable steps to respond appropriately and prevent further similar offenses.

How these seven elements are incorporated into an organization's compliance program depends on many things. For example, the particulars of a hospital's compliance program will not be identical to a managed care organization's compliance program because their activities, and therefore their risk areas, differ in various respects. Similarly, a small community hospital will not have the exact same compliance program as an academic medical center. Fortunately, the OIG has issued several CPGs for various sectors of the health care industry that are excellent resources when establishing (or learning about) compliance programs. The CPGs are available at http://www.oig.hhs.gov/fraud/complianceguidance.html.

Key laws every compliance professional should know

The variety and complexity of laws and regulations that touch on an organization's compliance program can be mind-boggling. Fear not! You will become familiar with all of them in time. But there are some laws that every compliance officer should be familiar with right from the start.

1. The Anti-kickback (AKB) Statute – 42 United States Code (U.S.C.) Section 1320a-7b

The AKB Statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any "remuneration" to induce or reward referrals of items or services reimbursable by a federal health care program. "Remuneration" is not limited to cash payment for referrals. Rather, if anything of value is exchanged (e.g., referral fees, payment of travel or conference expenses, tickets to sporting events, free or below market value rental space) between a referral source (e.g., a physician) and a party who provides items or services that are covered in whole or in part by Medicare or Medicaid (e.g., a hospital or DME vendor), the AKB Statute is implicated. Some courts have held that the AKB Statute is violated if even one purpose of the remuneration is to induce further referrals. Notably, the statute attributes liability to both parties involved in an impermissible kickback. Consequently, business practices that are common in other industries, such as taking clients to sporting events or paying for dinners or golf outings, can be construed as kickbacks when exchanged between Medicare/Medicaid referral sources and Medicare/Medicaid service providers.

The DOJ prosecutes criminal AKB cases. The OIG has civil authority to exclude from the Medicare and Medicaid programs a provider who has participated in a kickback scheme but has not been convicted under the criminal AKB statute. The OIG may also impose a civil monetary penalty (CMP) for an act described in the AKB Statute.

The OIG has the authority to promulgate safe harbors to the AKB Statue. Safe harbors are certain payment arrangements and business practices which, although potentially capable of inducing referrals of business under the Medicare and Medicaid programs, will not be treated as criminal offenses under the AKB Statute and will not serve as a basis for program exclusion. However, arrangements that don't meet a safe harbor are not illegal per se–they may or may not be, depending on the circumstances. The current safe harbors are located at 42 Code of Federal Regulations (CFR) Section 1001.952, which is available at http://www.access.gpo.gov/nara/cfr/waisidx_05/42cfr1001_05.html

Criminal penalties for violating the AKB Statute include a $25,000 fine and up to five years imprisonment. As mentioned earlier, the OIG can impose CMPs for AKB activities, as well as exclude the perpetrator from involvement in federal health care programs.

2. The Civil Monetary Penalties Law (CMPL) - 42 U.S.C. Section 1320a-7a

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The CMPL allows the OIG to impose monetary fines and assessments for a number of unacceptable practices. Examples include submitting false claims, accepting kickbacks and offering or providing inducements to Medicare and Medicaid beneficiaries that are likely to influence their choice of a Medicare or Medicaid provider. The full list of actions that can result in imposition of CMPs by the OIG is located at 42 CFR Section 1003.102, which is available at http://www.access.gpo.gov/nara/cfr/waisidx_05/42cfr1003_05.html

The OIG is authorized to seek different amounts of CMPs and assessments based on the type of violation at issue. For example, in a case of false or fraudulent claims, the OIG may seek a penalty of up to $10,000 for each item or service improperly claimed, and an assessment of up to three times the amount improperly claimed. In a kickback case, the OIG may seek a penalty of up to $50,000 for each improper act and an assessment of up to three times the amount of remuneration at issue. Administrative remedies include exclusion from federal health care programs.

3. The Civil False Claims Act – 31 U.S.C. Sections 3729 -3733

Signed by President Lincoln in 1863, the civil False Claims Act (FCA) makes it illegal to present (or cause to be presented) a claim to the federal government for payment or approval when the person or entity submitting the claim knows that the claim is false or fraudulent. Amendments to the FCA in 1986 strengthened its efficacy and led to its use in the health care industry, particularly in billing and coding areas (e.g., upcoding, unbundling, billing for medically unnecessary services, etc.)

"Claim" is any request or demand for money if the federal government provides any portion of the sum requested. Therefore, when a doctor or hospital bills Medicare for a service, a claim has been submitted to the federal government for payment.

The required intent is actual knowledge, deliberate ignorance, or reckless disregard of the truth or falsity of the claim. For example, when the DOJ suspects that a hospital has been upcoding its diagnosis-related group codes, (a potential FCA situation), the DOJ will ask if the hospital was aware of Medicare fiscal intermediary bulletins on this issue, is the Medicare rule understandable, did the hospital ever contact the Centers for Medicare and Medicaid Services (CMS) for guidance on the issue, and so on. These questions are asked to assess intent.

Mere submission of a claim is sufficient to sustain an action under the FCA. Actual payment or approval of a claim is not required.

Penalties of $5,500- $11,000 per claim can be imposed, as well as an assessment of up to three times the damages sustained by the government as a result of the false claim. Administrative remedies include program exclusion or a government-imposed compliance program.

Under the FCA, a private person, known as a qui tam relator, can initiate an FCA action on behalf of the federal government. The primary purpose of this provision is to give whistleblowers incentives to help the government discover and prosecute fraudulent claims by sharing a percentage of the recovery. If the government decides to proceed with a case initiated by a qui tam relator, and if the government is successful in winning the action, the relator gets 15%-25% of the proceeds. If the government declines to proceed with the case, but the relator wins or settles the case on his or her own, he or she is entitled to 25%-30% of the proceeds, plus reasonable costs and attorney's fees. Disgruntled current and former employees and competitors are common qui tam relators.

4. The Health Insurance Portability and Accountability Act (HIPAA) – Public Law 104-191; Social Security Act Section 1128C(a)

Nowadays, when you say "HIPAA," everyone in health care thinks of the confidentiality of patient information. But the HIPAA statute of 1996 was very broad and touched on a number of areas, including fraud and abuse. Among its anti-fraud and abuse measures, HIPAA appropriated dedicated funding to fight fraud and abuse and created new federal criminal offenses for health care fraud regardless of payer. It also required the establishment of a national Health Care Fraud and Abuse Control Program (HCFAC). HCFAC is under the joint direction of the Attorney General of the DOJ and the Secretary of HHS, the latter acting through the OIG. The HCFAC program is designed to coordinate federal, state, and local law enforcement activities with respect to health care fraud and abuse. Under HIPAA, an amount equaling recoveries from health care investigations (i.e., criminal fines, forfeitures, civil settlements and judgments, and administrative penalties) must be deposited in the Medicare Trust Fund. HHS and DOJ issue annual reports detailing the amounts deposited and appropriated to the trust fund and the source of such deposits. More information on HCFAC, is available at http://oig.hhs.gov/publications/hcfac.html#1

5. The Physician Self-Referral Act (Stark Law) – 42 U.S.C. Section 1395nn

The Physician Self-Referral Law (known as the Stark Law because its sponsor was Congressman Pete Stark) prohibits a physician from referring Medicare and Medicaid patients for certain designated health services

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(DHS) to entities with which the physician or the physician's immediate family member has a financial relationship, unless an exception applies. The DHS list is quite comprehensive and includes laboratory services, physical therapy, occupational therapy, speech therapy, and inpatient and outpatient hospital services (see 42 CFR Section 411.351 for the full DHS list). Likewise, the statutory definitions of "physician," "immediate family member," "referral," and "financial relationship" are of consequence. Much like the AKB Statute, a "financial relationship" exists whenever anything of value ("remuneration") passes from the DHS-provider to the physician.

In addition to penalizing the physician, the Stark Law also prohibits the DHS provider from billing for any services rendered or goods delivered as a result of a prohibited referral. The goal of the law is to ensure that a physician's decision to refer is based on the best interest of the patient and not the physician's financial interest in the entity that provides the services or items. As "they" say, the road to hell is paved with good intentions. The complexity of the regulations implementing the Stark Law (see 42 CFR Sections 411.350-361) bears this out.

Stark is a strict liability statute. This means that the law is violated if a prohibited referral is made and does not meet the specific requirements of the applicable exception. Whether the physician or DHS provider intended to violate the statute is irrelevant. The current exceptions, which are similar but not identical to the AKB safe harbors, are available at 42 CFR Section 411.355 -357.

Sanctions for Stark violations include:

(1) denial of payment for services resulting from prohibited referral;
(2) refund of any payment made by CMS to an entity furnishing DHS as a result of a prohibited referral;
(3) CMP of up to $15,000 per service plus an assessment of not more than three times the amount claimed;
(4) CMP of up to $100,000 for circumvention schemes;
(5) CMP of not more than $10,000 per day for failure to comply with certain reporting requirements;
(6) program exclusion; and
(7) potential prosecution under the FCA.

With the exception of lawyers, most compliance professionals are not required to understand the complexities of the Stark Law. Compliance professionals do need to recognize situations where the Stark Law is implicated (almost any relationship with a DHS referral-generating physician where remuneration of some sort is involved) and bring these situations to the attention of a knowledgeable attorney who can advise as to the application of the law in that scenario.

When analyzing the Stark Law, the questions to ask include:

- Is there a financial relationship between the physician (or immediate family member) and the entity providing DHS services?
- If so, does the physician make referrals to the entity for DHS?
- If so, are the services payable or paid by Medicare or Medicaid?
- If so, do any of the Stark statutory exceptions apply?
- If so, does the arrangement meet all of the qualifications of the applicable exception?

CMS, which is responsible for the regulations implementing the Stark Law, has a Physician Self-Referral Home Page, available at http://www.cms.hhs.gov/PhysicianSelfReferral/.

Note: The Stark Law and the AKB Statute are NOT identical. It is possible to be in compliance with one while simultaneously violating the other. Transactions between physicians and other entities must be analyzed separately under each statute.

Valuable Internet resources (and how to use them)

Once you master the basics of compliance, the challenge is to stay on top of compliance-related issues in your segments of the health care industry. Of course, joining a professional organization—such as HCCA—is an excellent way of staying up to date.

Another extremely useful practice is to develop a list of Internet sites that address issues that you are responsible for and consult them on a regular basis (daily if necessary). Your list will typically include federal and state agencies that regulate health care in some way (e.g., CMS, OIG, or state departments of health or insurance) as well as law firms and professional or trade organizations that monitor issues that are important to your industry. Once you start using the Internet for this purpose, you will find plenty of useful Web sites to include on your list!

A majority of my clients are health care institutions (i.e., hospitals, home care agencies, managed care organizations, etc.) and their businesses are involved with federal, state, and private health care insurance programs. HIPAA is also an issue for my clients. Here is a partial list of Web sites and recommendations for how often to use them. You may use this list as a jumping off point to start yours.

Visit daily

- Federal Register - http://www.access.gpo.gov/su_docs/fedreg/frcont06.html

Note: The Federal Register is the official document that the federal agencies use to promulgate new or revised rules and regulations. It is the first Web site I go to every day. I typically

scroll down to the CMS and HHS sections, the latter of which includes OIG notices.

- CMS - http://www.cms.hhs.gov/apps/media/

Note: I routinely search the press releases and fact sheets for current information.

- Medicare Advantage What's New Home Page - http://www.cms.hhs.gov/HealthPlansGenInfo/02_WhatsNew.asp#TopOfPage
- OIG What's New Home Page - http://www.oig.hhs.gov/w-new.html
- HHS http://www.hhs.gov/ (Hint: look to right for "News")
- American Health Lawyers Association http://www.healthlawyers.org/ (Hint: click on the News Center tab and then on the "Of Note" drop down)
- Kaiser Network - http://www.kaisernetwork.org/ (Daily Reports)
- Health Care Compliance Association http://www.hcca-info.org/am/Template.cfm?Section=Home
- Island Peer Review Organization (IPRO) http://providers.ipro.org/index
- NYS Attorney General Health Bureau Home Page - http://www.oag.state.ny.us/health/health_care.html
- NYS Department of Health - http://www.health.state.ny.us/
- NYS Department of Insurance Circular Letter Index - http://www.ins.state.ny.us/circindx.htm
- NYS Department of Insurance, Opinions of the Office of General Counsel - http://www.ins.state.ny.us/ropi2006.htm
- NYS Register - http://www.dos.state.ny.us/info/register/2006.htm
- NYS Senate and Assembly Floor Calendars http://public.leginfo.state.ny.us/menugetf.cgi?COMMONQUERY=CALENDAR
- Office for Civil Rights HIPAA Privacy Home Page - http://www.hhs.gov/ocr/hipaa/

Note: Internet access to the various parts of Volume 42 of the CFR is available by going to - http://www.access.gpo.gov/nara/cfr/waisidx_05/42cfrv2_05.html

Please Note: The CFR is updated every October (or thereabout). Consequently, on or after October 2006, the "waisidx_05" and the "05.html" within the URL will need to be changed to "waisidx_06" "06.html" in order to get the current version of the regulations. ■

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